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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/833,169

04/11/2001

Andrew G. Lee

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1529

7590

06/26/2006

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EXAMINER

WEBMAN, EDWARD J

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/833,169	Applicant(s) LEE ET AL.	
	Examiner Edward J. Webman	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 10-12, 40-48, 50-53 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-12, 46-48, 52 and 53 is/are allowed.
- 6) ☒ Claim(s) 1-5, 40-45, 50 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1, 2, 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Place et al.

Place et al teach a composition for treating sexual dysfunction. Estrogen antagonists including tamoxifen, raloxifene, centchroman, and droloxifene are disclosed (column 8 lines 27-35, 49-53).

Applicants argue that the “consisting of” language in claim 1 overcomes the reference, citing MPEP 2111.03 for authority that the effect of the phrase is to exclude any element, step, or ingredient not specified in the claim. However, the exclusion is in the alternative, supporting the interpretation that, in a method claim, it is the steps that are so limited, not necessarily the composition. Therefore, the rejection *supra* is maintained.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4, 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Place et al.

Place et al is discussed above. As to the particular claimed compounds, applicants disclose them all as SERMS, synonymous with the older terminology “estrogen antagonist” (Halonen et al col. 1 lines 40-42).

It would have been obvious to one of ordinary skill to use the claimed compounds in the method of Place et al in view of their known function as estrogen agonists/antagonists as stipulated by applicants. No criticality has been shown for any particular compound, In re Boesch USPQ 215 (CCPA 1980).

Applicants argue that Place et al does not teach 3.' 5' cyclic GMP elevators. However, they are claimed as merely optional. As explained for the 102 rejection, the effect of “consisting of”, in view of the alternative language in MPEP 2111.03, is interpreted as applying only to the method steps, not the composition.

Claims 5, 45, 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Place et al in view of Chiu et al.

Place et al is discussed above. As to the particular claimed compounds, applicants disclose them all as SERMs, synonymous with the older terminology “estrogen antagonist” (Halonen et al col. 1 lines 40-42).

It would have been obvious to one of ordinary skill to use the claimed compound in the method of Place et al in view of their known function as an estrogen agonists/antagonist as stipulated by applicants. No criticality has been shown for any particular compound, In re Boesch USPQ 215 (CCPA 1980). As to the claimed tartrate, Chiu et al teach the tartrate as a means of isolating the (-) optical isomer (abstract, column 1 line 66-column 2 line 8). Thus, it

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would have been further obvious to one of ordinary skill to use the tartrate salt, because the (-) optical isomer is isolated as the tartrate. As to the claimed pre and post-menopausal administration, it is well known, even to the layman, that female sexual dysfunction may occur at any age, thus, one of ordinary skill would recognize the obvious method as applicable to the claimed subjects.

Applicants argue that Place et al doesn't teach 3', 5' cyclic GMP elevators. Again, they are claimed as merely optional. As explained for the 102 rejection, the effect of "consisting of", in view of the alternative language in MPEP 2111.03, is interpreted as applying only to the method steps, not the composition.

Claims 1-5, 40-45, 50-51 are rejected. Claims 10-12, 46-48, 52-53 are allowed.


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan, can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500